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## II. Background and Statutory Findings

In the **Federal Register** of December 30, 1998 (63 FR 71920) (FRL-6050-1), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, as amended by the Food Quality Protection Act (FQPA) (Public Law 104-170), announcing the filing of a pesticide tolerance petition (PP 8E4992) by Huntsman Corporation, Houston, Texas. This notice included a summary of the petition prepared by the petitioner Huntsman. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.1001(c) be amended by establishing an exemption from the requirement of a tolerance for residues of propylene carbonate, also known as 1,3-Dioxolan-2-one, 4-methyl- (CAS Reg. No. 108-32-7).

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . ."

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

## III. Human Health Assessment

### A. Toxicological Profile

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by propylene carbonate are discussed in this unit. The Agency has reviewed 12 toxicity studies using propylene carbonate as the test substance. The results of those reviews are listed in the following Table 1:

TABLE 1.—TOXICITY STUDIES USING PROPYLENE CARBONATE

Study Type	Results
Acute oral (rat)	LD <sub>50</sub> > 5,000 mg/kg (Toxicity Category IV)
Acute dermal (rabbit)	LD <sub>50</sub> > 2,000 mg/kg (Toxicity Category III)
Primary eye irritation (rabbit)	Not a significant ocular irritant (Toxicity Category III)
Primary dermal irritation	(Toxicity Category IV)
Developmental (rat)	Maternal NOAEL = 1,000 mg/kg/day Maternal LOAEL = 3,000 mg/kg/day based on mortality, clinical signs and decreased food consumption Developmental NOAEL = 3,000 mg/kg/day Developmental LOAEL = 5,000 mg/kg/day based on increase in skeletal variations
113-week feeding (rat)	NOAEL = equal to or greater than 5,000 mg/kg/day (HTD - highest dose tested) LOAEL = would be greater than 5,000 mg/kg/day

TABLE 1.—TOXICITY STUDIES USING PROPYLENE CARBONATE—Continued

Study Type	Results
113-week inhalation (rat) with neurotox	NOAEL = 0.5 mg/L/day LOAEL = 1.0 mg/L/day based on clinical signs in both sexes No evidence of neurotoxic potential
Cancer dermal (skin-painting) (mouse)	Negative, but dosing was considered inadequate
9-day inhalation (rat)	NOAEL = not determined - effects seen at lowest dose tested LOAEL = 1 mg/L/day based on clinical signs of toxicity, ocular irritation
Mouse micronucleus	Not mutagenic
UDS	Negative
Gene mutation (S. typhimurium)	Negative

### B. Structure Activity Relationship Assessment

For propylene carbonate, toxicity was assessed, in part, by a process called structure-activity-relationship (SAR). In this process, the chemical's structural similarity to other chemicals (for which data are available) is used to determine toxicity. For human health, this process, can be used to assess absorption and metabolism, mutagenicity, carcinogenicity, developmental and reproductive effects, neurotoxicity, systemic effects, immunotoxicity, and sensitization and irritation. This is a qualitative assessment using terms such as good, not likely, poor, moderate, or high.

For propylene carbonate the SAR assessment determined that the chemical was not structurally related to any known carcinogens. The following human exposures were examined as part of the analysis: Inhalation, dermal, exposures to the eyes, and drinking water. Absorption of propylene carbonate is expected to be good (well-absorbed) via all routes (oral, dermal and inhalation) based on physical/chemical properties. There are concerns for effects on the liver and kidneys, solvent-type neurotoxicity and developmental toxicity at high dose levels, and irritation to mucous